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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,333	03/05/2002	Robert B. Dickson	P 0280655	4097

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EXAMINER	
LUCAS, ZACHARIAH	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 06/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/936,333	DICKSON ET AL.	
	Examiner	Art Unit	
	Zachariah Lucas	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 September 2001*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-33* are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-8, 20, 21 (note- claim 21 is treated as though it depends from claim 20 rather than claim 18), drawn to methods for the treatment of a malignancy, a pre-malignant condition, or a pathologic condition through the administration of a matriptase modulating compound.

Group II, claim(s) 9-11, drawn to nucleic acids encoding matriptase (Note-the sequences indicated in claim 9 are not nucleic acids, correction is required if the applicant elects this invention).

Group III, claim(s) 12, drawn to methods of producing recombinant matriptase (Note-the sequences indicated to be coding sequences in the claims are not nucleic acids, correction is required if the applicant elects this invention).

Group IV, claim(s) 13-14, drawn to matriptase proteins or polypeptides (Note, SEQ ID NO: 4 is not a protein or polypeptide as indicated in the claim, correction is required if applicant elects this invention).

Group V, claim(s) 15-19, drawn to antibodies to the matriptase protein.

Group VI, claim(s) 22 and 33 in part, drawn to methods for the identification of compounds that bind to the single-chain form or the Clr/Cls domains, and thereby inhibit activation or dimerization of the single-chain protein into the two-chain form.

Group VII, claim(s) 22 and 33 in part, drawn to methods for the identification of compounds that bind to the two-chain form of matriptase and thereby inhibits matriptase catalytic activity.

Group VIII, claim(s) 23-27, and 29-32, drawn to methods for the in vivo diagnosis of a pre-malignant lesion, a malignancy, or a pathologic condition.

Group IX, claim(s) 28, drawn to an in vitro method for the diagnosis of a pre-malignant lesion, a malignancy, or a pathologic condition.

For each of Groups I, V, VIII, or IX above, restriction to one of the following is also required under PCT Rule 13.1 and under 35 U.S.C. §§ 121 and 372. Therefore, election is required of one of Groups I- IX, and, if one of Groups I, V, VIII, or IX are elected, to one of inventions (1) or (2). Subgroups 1 and 2 represent the elected invention wherein the matriptase is in 1) single-chain form or 2) two-chain form.

For Group I above, restriction to one of the following is also required under PCT Rule 13.1 and under 35 U.S.C. §§ 121 and 372. Therefore, election is required of one of Groups I- IX, and, if Groups I is elected, to one of inventions (A)-(K). Subgroups (A)-(K) represent the elected invention wherein the condition being treated is

(A) atypical ductal hyperplasia of the breast;
(B) actinic keratosis (AK);
(C) leukoplakia;
(D) Barretts epiethlium (columnar metaplasia) of the esophagus;
(E) ulcerative colitis;
(F) adenomatous colorectal polyps;
(G) erythroplasia of Queyrat;
(H) Bowen's disease;
(I) bowenoid papulosis;
(J) vulvar intraepithelial neoplasia (VIN); or
(K) displastic changes to the cervix.

2. The inventions listed as subgroups to Group I do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the common technical feature of these inventions is the treatment of the conditions with a matriptase modulating agent, an example of which is identified as Bowman-Birk inhibitor. Bowman-Birk inhibitors are disclosed in the art as useful for the treatment of such conditions. See e.g., Kennedy et al., U.S. Patent 5,505,946. The common feature of these inventions is known in the art, it is not a common special technical feature. Unity is therefore lacking.

3. The inventions listed as subgroups to Groups I-IX do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: each of these inventions relates to a distinct compound or method from the others.

Sequence Listing

4. It is noted that, throughout the specification and the claims, the application refers to sequences in a manner inconsistent with the sequences indicated in the sequence listing. E.g., SEQ ID NO: 1 is indicated to be a nucleic acid and SEQ ID NO: 4 is indicated to be a protein. In view of the above, the specification is objected to for referring to protein or nucleic acid sequences without also identifying them by the sequence identifier assigned to them in the sequence listing as required by 37 CFR 1.821(d). The examiner would like to bring the applicant's attention to the following excerpt from MPEP §2422.03:

> 37 CFR 1.821(d) requires the use of the assigned sequence identifier in all instances where the description or claims of a patent application discuss sequences regardless of whether a given sequence is also embedded in the text of the description or claims of an application. This requirement is also intended to permit references, in both the description and claims, to sequences set forth in the "Sequence Listing" by the use of assigned sequence identifiers without repeating the sequence in the text of the description or claims. Sequence identifiers can also be used to discuss and/or claim parts or fragments of a properly presented sequence. For example, language such as "residues 14 to 243 of SEQ ID NO:23" is permissible and the fragment need not be separately presented in the "Sequence Listing." Where a sequence is embedded in the text of an application, it must be presented in a manner that complies with the requirements of the sequence rules.

The applicant is therefore required to amend the specification and the claims to comply with 37 CFR 1.821(d).

Conclusion

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

6. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Z. Lucas
Patent Examiner

James C Housel 6/1/04

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